The opinion in support of the decision being entered today was <u>not</u> written for publication and is <u>not</u> binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

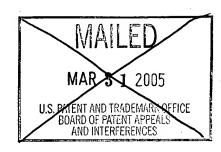
Ex parte JAMES R. LARKINS, DAVID D. SONGSTAD, WILLIAM L. PETERSEN, HONGYI ZHANG, MICHAEL T. MANN, MICHAEL SPENCER, and NANCY G. WILLETTS

REMAILED

APR 0 7 2005

U.S. PATENT AND TRADEMARK OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES Application No. 2004-15031 Application No. 09/606,808

ON BRIEF



Before SCHEINER, ADAMS and GREEN, <u>Administrative Patent Judges</u>.

ADAMS, <u>Administrative Patent Judge</u>.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 2, 3, 7-17 and 22-39. The examiner has indicated that claims 1, 4-6 and 18-21 are allowable. Answer, page 2.

¹ This appeal is substantially similar to Appeal No. 2004-1506, Application No. 09/788,334; Appeal No. 2004-1968, Application No. 10/00,0311; Appeal No. 2004-2317, Application No. 09/771,938; Appeal No. 2004-2343, Application No. 09/772,520; and Appeal No. 2005-0396, Application No. 10/077,589, which all share the same assignee, Monsanto Company, the parent of wholly-owned subsidiary DeKalb Genetics Corporation. Accordingly we have considered these appeals together.

Claims 2, 8-10, 14, 25, 26, 29 and 30 are illustrative of the subject matter on appeal and are reproduced below. In addition, for convenience, we have reproduced allowable claims 1 and 4 below:

- 1. Inbred corn seed of the corn plant LIZL5, a sample of said seed having been deposited under ATCC Accession No. PTA-2192.
- 2. The inbred corn seed of claim 1, further defined as an essentially homogeneous population of inbred corn seed.
- An inbred corn plant produced by growing the seed of the inbred corn plant LIZL5, a sample of said seed having been deposited under ATCC Accession No. PTA-2129.
- A corn plant capable of expressing all the physiological and morphological characteristics of the inbred corn plant LIZL5, a sample of the seed of said inbred corn plant LIZL5 having been deposited under ATCC Accession No. PTA-2192.
- The corn plant of claim 8, further comprising a cytoplasmic or nuclear gene conferring male sterility.
- 10. A tissue culture of regenerable cells of inbred corn plant LIZL5, wherein the tissue regenerates plants capable of expressing all the physiological and morphological characteristics of the inbred corn plant LIZL5, a sample of the seed of said corn plant LIZL5 having been deposited under ATCC Accession No. PTA-2192.
- 14. An inbred corn plant cell of the corn plant of claim 8, said cell comprising:
 - (a) an RFLP genetic marker profile^[2] in accordance with the profile shown in Table 6; or
 - (b) a genetic isozyme typing profile in accordance with the profile shown in Table 7.
- 25. The corn plant of claim 4, further comprising a single locus conversion.

² We note that claims 14 and 17 appear to include a typographical error in reference to RFLP genetic marker profiles. As the examiner points out (Answer, page 12), "Table 6 in the specification actually shows SSR profiles, not RFLP genetic marker profiles as indicated in claims 14 and 17." Therefore, prior to any further action on the merits, we encourage the examiner and appellants to clarify this issue on the record.

- 26. The corn plant of claim 25, wherein the single locus was stably inserted into a corn genome by transformation.
- 29. A method of preparing a transgenic maize cell comprising:
 - a) Providing cells of inbred corn plant LIZL5, a sample of the seed of the inbred LIZL5 having been deposited under ATCC Accession No. PTA-2192;
 - b) Contacting said cells with a pre-selected DNA; and
 - c) Identifying at least a first transgenic cell of inbred corn plant LIZL5 which has been transformed with said pre-selected DNA.
- 30. The method of claim 29, further comprising the step of:
 - d) Regenerating a fertile transgenic plant from said transgenic cell.

The references relied upon by the examiner are:

Hunsperger et al. (Hunsperger)

5,523,520

Jun. 4, 1996

Eshed et al. (Eshed), "Less-Than-Additive Epistatic Interactions of Quantitative Trait Loci in Tomato," Genetics, Vol. 143, pp. 1807-17 (1996)

Kraft et al. (Kraft), "Linkage Disequilibrium and Fingerprinting in Sugar Beet," Theoretical and Applied Genetics, Vol. 101, pp. 323-36 (2000)

GROUNDS OF REJECTION

Claim 2 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "an essentially homogeneous population of inbred corn seed."

Claim 3 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "essentially free from hybrid seed."

Claim 7 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "[a]n essentially homogeneous population of corn plants produced by growing the seed of the inbred corn plant LIZL5."

Claims 8, 10-13³ and 37 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "capable of expressing," as it is used in claims 8 and 10-13; and the term "preparable," as it is used in claim 37.

Claims 9 and 25 stand rejected under 35 U.S.C. § 112, second paragraph as failing to limit the scope of the independent claim from which they depend.

Claims 14 and 17 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "in accordance with."

Claim 25 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of "comprising a single locus conversion."

Claim 26 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the article 'a' in the recitation 'wherein the single locus was stably inserted into <u>a</u> corn genome."

Claim 28 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrases "yield enhancement," "improved nutritional quality," and "enhanced yield stability."

Claims 14-17 and 22-39 stand rejected under the written description provision of 35 U.S.C. § 112, first paragraph.

Claims 25-39 stand rejected under the enablement provision of 35 U.S.C. § 112, first paragraph.

³ We note the examiner's assertions (Answer, page 11), "claim 11 remains rejected because it depends from claim 10," and "claim 12 remains rejected because it depends from claim 11." Accordingly, we have included claims 11 and 12 in the statement of this rejection.

We reverse.

BACKGROUND

The present "invention relates to inbred corn seed and plants designated LIZL5, and derivatives, tissue cultures thereof, methods of transformation of plants or parts thereof of the plant designated LIZL5 and transformants derived thereof." Specification, page 1. According to appellants (specification, page 25), "[a] description of the physiological and morphological characteristics of corn plant LIZL5 is presented in Table 3" of the specification, pages 25-27. On this record the examiner has indicated that claims drawn to plants, plant parts, and seed of the corn variety designated LIZL5 are allowable. See e.g., claims 1, and 4-6, and Answer, page 2, wherein the examiner states "[c]laims 1, [and] 4-6 ... are allowed."

A second aspect of the present invention comprises hybrid plants and processes "for producing [first generation (F₁) hybrid⁴] corn seeds or plants, which ... generally comprise crossing a first parent corn plant with a second

⁴ We recognize the examiner's statement (Answer, page 3), "[c]laim 24 was objected to in the Office [A]ction mailed 16 July 2003, as being in improper dependent form for failing to further limit the subject matter of previous claim. Appellants did not address this objection." An objection to a claim, however, is the subject matter of a petition, and is not properly before us on appeal. Nevertheless, we make the following observation regarding claim 24, and encourage the examiner and appellants to work together to remedy this issue, prior to any further action on the merits.

According to appellants' specification (page 19), a F₁ hybrid is "[t]he first generation progeny of the cross of two plants." Therefore, as we understand the prosecution history as well as the language of the claims, claims 22 and 23 to refer to F₁ hybrids. In this regard, we note that similar claims, directed to a different corn variety, were presented for our review in Appeal Nos. 2004-1506 and 2004-2317. During the oral hearing in Appeal Nos. 2004-1506 and 2004-2317, appellants' representative confirmed that all claims drawn to hybrid plants or hybrid seeds (see e.g., claims 24 and 25 of Appeal Nos. 2004-1506 and 2004-2317) refer to F₁ hybrids. Accordingly, it appears that claim 24 fails to further limit claim 23 from which it depends.

parent corn plant, wherein at least one of the first or second parent corn plants is the inbred corn plant designated LIZL5." Specification, pages 7-8. On this record the examiner has indicated that claims drawn to a process of producing corn seed wherein the process comprises crossing a first parent corn plant with a second parent corn plant are allowable. See e.g., claims 18-21 and Answer, page 2, wherein the examiner states claims "18-21 are allowed."

A third aspect of the present invention comprises single locus converted plants of the corn variety LIZL5. Specification, page 6. As appellants explain (specification, page 21, emphasis added), single locus converted (conversion) plants are those plants

which are developed by a plant breeding technique called backcrossing wherein <u>essentially all</u> of the desired morphological and physiological characteristics of an inbred are recovered in addition to the characteristics conferred by the single locus transferred into the inbred <u>via</u> the backcrossing technique. A single locus may comprise one gene, or in the case of transgenic plants, one or more transgenes integrated into the host genome at a single site (locus).

As appellants explain (specification, page 29):

Many single locus traits have been identified that are not regularly selected for in the development of a new inbred but that can be improved by backcrossing techniques. Single locus traits may or may not be transgenic; examples of these traits include, but are not limited to, male sterility, waxy starch, herbicide resistance, resistance for bacterial, fungal, or viral disease, insect resistance, male fertility, enhanced nutritional quality, industrial usage, yield stability, and yield enhancement. These genes are generally inherited through the nucleus, but may be inherited through the cytoplasm. Some known exceptions to this are genes for male sterility, some of which are inherited cytoplasmically, but still act as single locus traits.

A final aspect of the present invention is directed to a method of preparing a transgenic maize cell comprising the use of cells of inbred corn plant LIZL5.

See e.g., claim 29. According to appellants' specification (page 10), the "invention provides a method of preparing a transgenic maize cell comprising: a) providing cells of inbred corn plant LIZL5, b) contacting the cells with a preselected DNA; and c) identifying at least a first transgenic cell of inbred corn plant LIZL5 which has been transformed with the pre-selected DNA."

Against this backdrop, we now consider the rejections of record.

DISCUSSION

Definiteness:

Claims 2, 3, 7-17, 25-28, and 37-39 stand rejected under 35 U.S.C. § 112, second paragraph. For the following reasons we reverse.

<u>Claim 2</u>

Claim 2 depends from independent claim 1, and stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "an essentially homogeneous population of inbred corn seed...." Answer, page 4. According to the examiner (id.), "[g]iving claim 2 its plain meaning, the inbred corn seed of claim 1 must, by definition, be a homogeneous population." Thus, the examiner finds (id.), the "essentially homogeneous' language [in claim 2] ... appear[s] to be superfluous."

However, as disclosed in appellants' specification (page 5),

[e]ssentially homogeneous populations of inbred seed are those that consist essentially of the particular inbred seed, and are generally free from substantial numbers of other seed, so that the

inbred seed forms between about 90% and about 100% of the total seed, and preferably, between about 95% and about 100% of the total seed.

Accordingly, we disagree with the examiner's assertion (Answer, page 6) that claim 2 is unclear simply because it may contain seed other than the seed of the corn variety LIZL5. We remind the examiner that claim language must be analyzed "not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary skill in the pertinent art." In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971). Accordingly, it is our opinion that a person of ordinary skill in the art would recognize that an essentially homogeneous population of seed of the corn variety LIZL5 is a population of seed that is generally free from substantial numbers of other seed, e.g., wherein corn variety LIZL5 seed forms between about 90% and about 100% of the total seed in the population.⁵

Accordingly, we reverse the rejection of claim 2 under 35 U.S.C. § 112, second paragraph.

Claim 3

According to the examiner (Answer, page 5), claim 3 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "essentially free from hybrid seed," "for reasons similar to the rejection of

⁵ <u>Cf.</u> the examiner's statement (Answer, page 6), "if claim 2 were amended to read '[a]n essentially homogeneous population of corn seeds consisting essentially of seed the inbred corn seed of claim 1', the claim would have a definite meaning.

claim 2. Thus, the examiner recommends (<u>id.</u>), claim 3 be amended to read, "[a] population of corn seeds consisting essentially of the inbred corn seed of claim 1, and essentially free from hybrid seeds." Therefore, for the reasons, set forth in our discussion of the rejection of claim 2 under 35 U.S.C. § 112, second paragraph above, we agree with appellants (Brief, page 5), claim 3 "further defines ... claim [1] from which it depends by requiring that the seed be free of hybrid seed."

Accordingly, we reverse the rejection of claim 3 under 35 U.S.C. § 112, second paragraph.

Claim 7

Claim 7 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "[a]n essentially homogeneous population of corn plants produced by growing the seed of the inbred corn plant LIZL5...." Answer, page 6. According to the examiner (id.), "LIZL5 seed can only produce LIZL5 plants. ... [Therefore,] [t]he population can ... only consist of LIZL5 plants." Accordingly, the examiner finds it unclear "why the population is referred to as 'essentially homogeneous,' since such populations can comprise more than one variety of plant." Id.

As appellants disclose (specification, page 6), "[t]he population of inbred corn seed of the invention can further be particularly defined as being essentially free from hybrid seed. The inbred seed population may be separately grown to provide an essentially homogeneous population of inbred corn plants designated LIZL5." As we understand the claim, growing the seed of claim 3, for example,

would produce an essentially homogeneous population of corn plants of the corn variety LIZL5.6

In addition, we direct the examiner's attention to Appeal No. 2005-0396, wherein a claim similar to claim 7 was presented for our review. In Appeal No. 2005-0396, the examiner of record indicated that claim 14, directed to "[a]n essentially homogeneous population of corn plants produced by growing the seed of the corn variety I180580...." was allowable. Accordingly, we find that the examiner has treated claim 7 in a manner that is inconsistent with the prosecution of claim 14 in 2005-0396. As we understand it, the only difference between claim 14 as it appears in Appeal No. 2005-0396 and claim 7 before us in the instant appeal is the variety of corn seed from which the plant is produced.

Accordingly we reverse the rejection of claim 7 under 35 U.S.C. § 112, second paragraph.

Claims 8, 10-13 and 37

Claims 8, 10-13 and 37 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "capable of expressing," as it is used in claims 8 and 10-13; and the term "preparable" as it is used in claim 37. According to the examiner (Answer, page 8), the recitation of the phrase "capable of" in claims 8 and 10-13 "does not make clear if the plant actually

⁶ <u>Cf.</u> The examiner's statement (Answer, page 7), "[a]mending claim 7 to read, '[a]n essentially homogeneous population of corn plants produced by growing a population of corn seed consisting essentially of the seed of corn plant LIZL5...' would obviate this rejection."

expresses the traits, or when or under what conditions the traits are expressed." In this regard, the examiner finds (Answer, page 9),

while the plant has the capacity to express the characteristics, for some reason it may not. Certain characteristics of a plant are expressed only at certain times of its life cycle, and are incapable of being expressed at other times. The colors of flower parts such as silks, or fruit parts such as husks, are examples. The promoters of many genes conferring traits require a transcription factor to become active. Is a plant that has such a gene, but not the transcription factor, considered "capable of expressing" that gene, and the trait associated with that gene, and is such a plant encompassed by the claims?

To address the examiner's concerns, we find it sufficient to state that if a plant has the capacity to express the claimed characteristics it meets the requirement of the claim regarding "capable of," notwithstanding that due to a particular phase of the life cycle the plant is not currently expressing a particular characteristic. Alternatively, if a plant is incapable of expressing the claimed characteristics at any phase of the life cycle, because it lacks, for example, the "transcription factor" required for expression — such a plant would not meet the requirement of the claim regarding "capable of."

Here, we find the examiner's extremely technical criticism to be a departure from the legally correct standard of considering the claimed invention from the perspective of one possessing ordinary skill in the art. ⁷ In our opinion, a person of ordinary skill in the art would understand what is claimed. Amgen Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir. 1991).

⁷ Cf. Digital Equipment Corp. v. Diamond, 653 F.2d 701, 724, 210 USPQ 521, 546 (CA 1981).

Similarly, the examiner finds (Answer, page 16), the recitation of the term "preparable" in claim 37 "leaves open the possibility that the claimed fertile transgenic corn plant can be prepared by any other means." In our opinion, like "capable of" above, the claim requires that the plant be able to be produced by the process of claim 30. That a person of ordinary skill in the art may conceive of other ways to prepare the plant is of no concern. Alternatively, if a plant cannot be prepared according to the process of claim 30 it would be outside the scope of claim 37.

Accordingly we reverse the rejection of claims 8, 10-13 and 37 under 35 U.S.C. § 112, second paragraph.

Claims 9 and 25

Claim 9 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "a cytoplasmic or nuclear gene conferring male sterility. As we understand the examiner's argument (Answer, bridging paragraph, pages 9-10), since the plant set forth in claim 9 is male sterile it "cannot incorporate all the limitations of claim 8..." from which claim 9 depends. Similarly, the examiner finds it unclear whether the plant set forth in claim 25 has all the traits expressed by the plant of ... [claim] 5," from which claim 25 depends. Answer, page 13. In response, appellants assert (Brief, pages 7 and 9), claims 9 and 25 simply add a further limitation to the claims from which they depend. We agree.

For example, claim 9 reads on a corn plant capable of expressing all the physiological and morphological characteristics of the corn variety LIZL5, further

comprising a nuclear or cytoplasmic gene conferring male sterility. In our opinion, the claim reasonably apprises those of skill in the art of its scope.

Amgen, In our opinion, the same is true of claim 25. As set forth in Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir. 1985), "[i]f the claims, read in the light of the specifications, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more."

Accordingly we reverse the rejection of claims 9 and 25 under 35 U.S.C. § 112, second paragraph.

Claims 14 and 17

Claims 14 and 17 stand rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrase "in accordance with." According to the examiner (Answer, page 12), it is unclear if a plant "that generally follows the trend of the profile of Table 6, but which differs at one or a few loci, [would] be considered in 'conformity' or 'in accordance' with the profile of Table 6."

On this record, we understand the phrase "in accordance with" as it is used in claims 14 and 17 to mean "the same". Furthermore, as discussed supra, n. 2, claims 14 and 17 appear to include a typographical error in reference

⁸ <u>Cf.</u> Appeal Nos. 2004-1506 and 2004-2317, which use similar language for claims directed to different corn varieties. In this regard, we note that during the February 10, 2005 oral hearing in Appeal Nos. 2004-1506 and 2004-2317, appellants' representative confirmed that the phrase "in accordance with" was intended to mean "the same".

to RFLP genetic marker profiles of Table 6, whereas, Table 6 of appellants' specification illustrates SSR profiles, not RFLP genetic marker profiles. Stated differently, we understand the claims to read:

- 15. An inbred corn plant cell of the corn plant of claim 8, said cell comprising:
 - (c) the same SSR profile as shown in Table 6; or
 - (d) the same genetic isozyme typing profile as shown in Table 7.
- 17. The inbred corn plant of claim 8, comprising:
 - (a) the same SSR profile as shown in Table 6; or
 - (b) the same genetic isozyme typing profile as shown in Table 7.

Accordingly we reverse the rejection of claims 14 and 17 under 35 U.S.C. § 112, second paragraph.

Claim 26

Claim 26 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the article 'a' in the recitation 'wherein the single locus was stably inserted into <u>a</u> corn genome." According to the examiner (Answer, page 14), "[t]he recitation does not make clear if the genome is that of LIZL5 or that of a different corn plant."

According to appellants' specification (page 21, emphasis removed), a "Single Locus Converted (Conversion) Plant" refers to

[p]lants which are developed by a plant breeding technique called backcrossing wherein essentially all of the desired morphological and physiological characteristics of an inbred are recovered in addition to the characteristics conferred by the single locus transferred into the inbred <u>via</u> the backcrossing technique. A single locus may comprise one gene, or in the case of transgenic plants, one or more transgenes integrated into the host genome at a single site (locus).

Accordingly, we agree with appellants (Brief, bridging paragraph, pages 10-11), the single locus referred to in claim 26 may or may not have been directly inserted into the genome of the claimed plant. As we understand the claim, and arguments of record, claim 26 presents two possibilities: (1) the single locus is directly inserted into the claimed plant and nothing further need be done; or (2) the single locus is directly inserted into a different plant, which is then used to transfer the single locus to the claimed plant through use of the plant breeding technique known as backcrossing.

In our opinion, the claim reasonably apprises those of skill in the art of its scope. Amgen. Accordingly, we reverse the rejection of claim 26 under 35 U.S.C. § 112, second paragraph.

Claim 28

Claim 28 stands rejected under 35 U.S.C. § 112, second paragraph as indefinite in the recitation of the phrases "yield enhancement," "improved nutritional quality," and "enhanced yield stability." According to the examiner the terms "yield enhancement," "improved nutritional quality," and "enhanced yield stability" are relative and have no definite meaning. Answer, page 14.

On this record, appellants assert (Brief, page 13), it is "understood the enhancement of yield or yield stability and improved nutritional quality is relative to a plant lacking the single locus. The metes and bounds of the claim are thus fully understood by one of skill in the art and the use of the terms is not indefinite." On reflection, we agree with appellants. The fact that some claim language is not mathematically precise does not <u>per se</u> render the claim

indefinite. Seattle Box. Co. v. Industrial Crating & Packing, Inc., 731 F.2d 818, 826, 221 USPQ 568, 573-574 (Fed. Cir. 1984). As set forth in Shatterproof Glass, "[i]f the claims, read in the light of the specifications, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more." In our opinion, a person of ordinary skill in the art would have understood the enhancement of yield or yield stability and improved nutritional quality is relative to a plant lacking the single locus.

Accordingly we reverse the rejection of claim 28 under 35 U.S.C. § 112, second paragraph.

Written Description:

Claims 14-17 and 22-39 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification fails to adequately describe the claimed invention. For the following reasons, we reverse.

<u>Claims 22-24</u>

Claims 22-24 both ultimately depend from claim 18. On this record, the examiner has indicated that claims 18-21 are allowable. Answer, page 2. The examiner finds (Answer, page 18), claims 22-24 are drawn to a hybrid plant or seed "produced by crossing inbred corn plant LIZL5 with any second, distinct inbred corn plant."

As we understand it, based on this construction of claims 22-24, the examiner is of the opinion that since the hybrids inherit only ½ of their diploid⁹ set of chromosomes from the plant of corn variety LIZL5, a person of skill in the art would not have viewed the teachings of the specification as sufficient to demonstrate that appellants were in possession of the genus of hybrid seeds and plants encompassed by claims 22-24. See Answer, pages 23-24. According to the examiner (Answer, page 24), "[t]he fact that any hybrid plant will inherit half of its alleles from LIZL5 then does not provide sufficient description of the morphological and physiological characteristics expressed by the claimed hybrid plants."

There is no doubt that the expressed gene products of a hybrid plant, e.g., the morphological and physiological traits, of LIZL5 and a non-LIZL5 corn plant will depend on the combination of the genetic material inherited from both parents. See Answer, page 24. Nevertheless, we disagree with the examiner's conclusion (id.) that "[t]he fact that any hybrid plant will inherit half of its alleles from LIZL5 then does not provide sufficient description of the morphological and physiological characteristics expressed by the claimed hybrid plants."

On these facts, we find it necessary to take a step back and consider what is claimed. The claims are drawn to a F₁ hybrid seed (claim 22) or plant (claim 23) resulting from a cross between a plant of corn variety LIZL5 and a non-LIZL5 corn variety. The claims do not require the hybrid to express any particular

⁹ According to appellants' specification (page 19), diploid means "a cell or organism having two sets of chromosomes."

morphological or physiological characteristic. Nor do the claims require that a particular non-LIZL5 corn variety be used. 10 All that is required by the claims is that the hybrid has one parent that is a plant of corn variety LIZL5. Since the examiner has indicated that the seed and the plant of the corn variety LIZL5 are allowable (see claims 1 and 4), there can be no doubt that the specification provides an adequate written description of this corn variety. In addition, the examiner appears to recognize (see e.g., Answer, page 17) that appellants' specification describes an exemplary hybrid wherein one parent was a plant of the corn variety LIZL5. Accordingly, it is unclear to this merits panel what additional description is necessary.

As set forth in Reiffin v. Microsoft Corp., 214 F.3d 1342, 1345, 54

USPQ2d 1915, 1917 (Fed. Cir. 2000), the purpose of the written description requirement is to "ensure that the scope of the right to exclude, as set forth in the claims does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification." Here the hybrid seed or plant has one parent that is a plant of the corn variety LIZL5. To that end, to satisfy the written description requirement, the inventor "must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention" [emphasis added]. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). For the foregoing

¹⁰ According to appellants (Brief, page 14), "hundreds or even thousands of different inbred corn lines were well known to those of skill in the art prior to the filing [date] of the instant application, each of which could be crossed to make a hybrid plant with in the scope of the claims."

reasons it is our opinion that appellants have provided an adequate written description of the subject matter set forth in claims 24-26.11

We recognize the examiner's argument relating to SSR and isozyme markers (Answer, pages 26-27), as well as the examiner's arguments concerning a correlation between the hybrid's genome structure and the function of the hybrid plant (Answer, page 25). However, for the foregoing reasons, we are not persuaded by these arguments.¹²

Claims 14-17

According to the examiner (Answer, page 19), while the specification provides the locus names and allele numbers of the SSR markers, the specification does not provide the actual nucleotide sequences that make up the markers. According to the examiner (id.), "names of loci alone do not describe the structures of the markers themselves. Without a description of the sequences of the markers, one cannot confirm their presence." However, as the examiner recognizes (id.), "[t]he specification indicates on page 57, lines 17-18, that the SSR analyses were conducted at Celera AgGen, and on page 60, line 3, that primers used in the analyses are also from Celera AgGen." In this regard, appellants point out (Brief, page 15), "the service that was used to detect SSR markers is commercially available to the public." In other words, a person of

¹¹ Again, we note as set forth in n. 4, claim 24 does not appear to further limit the scope of claim 23 from which it depends.

¹² For the same reasons we are not persuaded by the examiner's assertion (Answer, page 22) that appellants' specification fails to provide an adequate written description of claims 38 and 39.

ordinary skill in the art could use the commercially available service provided by Celera AgGen, Inc. to determine whether a corn plant produced by growing a seed of the corn variety LIZL5 has an SSR profile which is the same as that shown in Table 6. Therefore, it is unclear to this panel why the examiner believes that such a disclosure fails to provide adequate written descriptive support for the claimed invention.¹³ Accordingly, we are not persuaded by the examiner's argument.

Regarding the isozyme typing profile, the examiner notes (Answer, page 19), "16 of the 18 isozyme markers of LIZL5 in Table 7 are also found in at least two other corn varieties, those of the other plants of Table 7." Based on this observation, the examiner concludes (id., emphasis added), "the markers in Table 6 are not adequate to distinguish the claimed hybrids from other corn plants, as other corn plants contain almost all of the same markers. [144]" We find the examiner's logic somewhat inconsistent, the examiner recognizes that isozyme typing profiles of "other corn plants" are different, yet concludes that the different isozyme profiles are inadequate to distinguish the claimed hybrids from other corn plants. Accordingly, we are not persuaded by the examiner's argument.

¹³ We are not persuaded by the examiner's assertion (Answer, page 30) "that the [commercially available] service used to detect SSR markers is currently available is not a guarantee that it will remain so for the life of a patent issuing from the application." <u>Cf. In re Metcalfe</u>, 410 F.2d 1378, 1382, 161 USPQ 789, 792-3 (CCPA 1969).

¹⁴ Stated differently, the examiner recognizes that the isozyme typing profiles of the corn plants are different.

In addition, we direct the examiner's attention to claims 6 and 11 of Appeal No. 2005-0396. As we understand it, notwithstanding differences in the SSR and isozyme profiles, the disclosure in the specification as well as the language of the claims is substantially similar to that of the instant application. Nevertheless, the examiner in Appeal No. 2005-0396 apparently found that appellants' specification provided an adequate written description of the claimed invention as no rejection of claims 6 and 11 was made under the written description provision of 35 U.S.C. § 112, first paragraph in Appeal No. 2005-0396. Accordingly, we find that the examiner has treated claims 14-17 in a manner that is inconsistent with the prosecution of similar claims in related application 10/077,589, which is the subject matter of Appeal No. 2005-0396.

For the foregoing reasons, we are not persuaded by the examiner's arguments.

Claims 25-28

According to the examiner (Answer, page 20), "[c]laims 25-28 are drawn towards LIZL5 plants further comprising a single locus conversion, or wherein the single locus was stably inserted into a corn genome by transformation." The examiner finds, however, that "the specification does not describe identified or isolated single loci for all corn plant traits." Id. More specifically, the examiner finds (id.), claims 25-27 "broadly encompass single loci that have not been discovered or isolated." To the extent that the examiner is asserting that appellants have not provided an enabling disclosure of single loci that have not been identified, we note that to satisfy the written description requirement, the

inventor "must convey with reasonable clarity to those skilled in the art that, <u>as of the filing date sought</u>, he or she was in possession of the invention" [emphasis added]. Vas-Cath.

Nevertheless, it may be that the examiner's concern (Answer, page 34), is that "single genes that alone govern 'yield enhancement' or 'enhanced yield stability' have not been discovered." The examiner, however, provides no evidence to support the assertion that a person of ordinary skill in the art would not recognize that single loci for yield enhancement or yield stability are known in the art. In this regard, we note that appellants disclose (specification, page 29), "[m]any single locus traits have been identified ... examples of these traits include, but are not limited to, ... enhanced nutritional quality, industrial usage, yield stability, and yield enhancement." It appears that the examiner has overlooked appellants' assertion that single locus traits for yield stability and yield enhancement are well known in the art. To this end, we direct the examiner's attention to, for example, United States Patent No. 5,936,145 ('145)¹⁵, issued August 10, 1999, which is prior to the filling date of the instant application. For clarity, we reproduce claims 8, 29 and 39 of the '145 patent below:

- 8. A corn plant having all the physiological and morphological characteristics of corn plant 87DIA4, a sample of the seed of said corn plant having been deposited under ATCC Accession No. 203192.
- 29. The corn plant of claim 8, further comprising a single gene conversion.

¹⁵ We note that the assignee of the '145 patent is DeKalb Genetics Corporation. The assignee of the present application is Monsanto Company, the parent of wholly-owned subsidiary DeKalb Genetics Corporation.

39. The single gene conversion of the corn plant of claim 29, where the gene confers enhanced yield stability.

As we understand it, claim 39 of the '145 patent, is drawn to a corn plant which comprises a single gene conversion, wherein the gene confers enhanced yield stability. Thus, contrary to the examiner's assertion it appears, for example, that a single gene that confers enhanced yield stability was known in the art prior to the filing date of the instant application. We remind the examiner "a patent need not teach, and preferably omits, what is well known in the art." Hybritech Incorporated v. Monoclonal Antibodies, Inc. 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986).

We remind the examiner that the inquiry into whether the description requirement is met must be determined on a case-by-case basis and is a question of fact. In re Wertheim, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). A description as filed is presumed to be adequate; unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See e.g., In re Marzocchi, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description.

Accordingly, it is the examiner who has the initial burden of establishing by a preponderance of evidence that a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims.

Wertheim, 541 F.2d at 263, 191 USPQ at 97. On this record, the examiner

provides no evidence to support the assertion that single loci that govern, for example, yield enhancement or enhanced yield stability are not described.

For the foregoing reasons, we are not persuaded by the examiner's arguments.¹⁶

Summary

For the foregoing reasons, we reverse the rejection of claims 14-17 and 22-39 under the written description provision of 35 U.S.C. § 112, first paragraph.

Enablement:

Claims 25-39 stand rejected under the enablement provision of 35 U.S.C. § 112, first paragraph. The examiner finds (Answer, page 36), claims 27-30

are broadly drawn to inbred corn plant LIZL5 further comprising a single locus conversion; or to any method of preparing transgenic LIZL5 cells comprising contacting cells of inbred corn plant LIZL5 with any pre-selected DNA, having any function; or wherein said method further comprises regenerating a fertile transgenic plant; or a fertile transgenic plant produced by said method; or seed of said transgenic plant; or a plant grown from said seed.

According to the examiner (Answer, page 37), "[a] review of claim 25 indicates that it encompasses corn plant LIZL5, and therefore all of its morphological and physiological traits, and further comprising any single locus." While the examiner recognizes (id.), "[t]he practice of crossing two plant varieties, each expressing two different desired traits ... is well-established," the examiner finds (id.), "the specification does not teach any LIZL5 plants

¹⁶ For the same reasons we are not persuaded by the examiner's assertion (Answer, page 22) that appellants' specification fails to provide an adequate written description of claims 29-39.

comprising a single locus conversion produced by backcrossing, wherein the resultant plant retains all of its morphological and physiological traits in addition to exhibiting the single trait conferred by the introduced single locus." With reference to Hunsperger, Kraft, and Eshed, the examiner asserts (Answer, page 42), "[t]he rejection raises the issue of how linkage drag hampers the insertion of single genes alone into a plant by backcrossing, while recovering all of the original plant's genome."

Notwithstanding the examiner's assertions to the contrary, claims 25-39 do not require that the single locus conversion plant retain all of the morphological and physiological traits of the parent plant in addition to exhibiting the single trait conferred by the introduction of the single loci. Nor do claims 25-39 require that the resultant plant retain all of the original plant's genome in addition to the single locus transferred into the inbred via the backcrossing technique. As appellants explain (specification, bridging paragraph, pages 27-28, emphasis added),

[t]he term single locus converted plant as used herein refers to those corn plants which are developed by a plant breeding technique called backcrossing wherein <u>essentially all</u> of the desired morphological and physiological characteristics of an inbred are recovered in addition to the single locus transferred into the inbred via the backcrossing technique.

<u>See also</u> appellants' definition of single locus converted (conversion) plant at page 23 of the specification. We find nothing in the appellants' specification to indicate that the single locus converted plant retains <u>all</u> of the morphological and physiological traits, or <u>all</u> of the genome, of the parent plant in addition to the

single locus transferred <u>via</u> the backcrossing technique. Accordingly, we disagree with the examiner's construction of claims 25-39 as "directed to <u>exactly</u> plant LIZL5, further comprising the single locus.," which appears to disregard appellants' definition of a single locus converted plant. <u>See</u> Answer, page 43.

The examiner appreciates (Answer, page 37) that appellants' specification provides an example of a converted plant. While the examiner finds (id.), that this converted plant was not a LIZL5 converted plant, the examiner offers no evidence on this record that similar methodology used to produce the exemplified converted plant would not also be effective in producing a LIZL5 converted plant. Nor did the examiner provide evidence that the converted plant exemplified in appellants' specification did not retain essentially all of the desired morphological and physiological characteristics of the inbred in addition to the characteristics conferred by the single locus transferred into the inbred via the backcrossing technique.

Further, we recognize appellants' argument (Brief, page 24) that the examiner failed to establish a nexus between Hunsperger's discussion of petunias; Kraft's discussion of sugar beets; and Eshed's discussion of tomatoes, and the subject matter of the instant application - corn. Absent evidence to the contrary, we agree with appellants (id.), "[t]he [examiner's] indication^[17] that the references concerning petunias, sugar beets and tomatoes apply to corn is made without any support." That the examiner has failed to identify (Answer,

¹⁷ <u>See</u> Answer page 42, wherein the examiner asserts "[I]inkage drag appears to be a phenomenon that occurs in all plant types."

page 42) an example "in the prior art of plants in which linkage drag does not occur," does not mean that linkage drag is expected to occur in corn breeding, which according to appellants (Reply Brief, page 10) "is extremely advanced and well known in the art...." In this regard, we agree with appellants (Brief, bridging paragraph, pages 24-25; Accord Reply Brief, pages 7-8), the examiner has improperly placed the burden on appellants to demonstrate that the examiner's unsupported assertion is not true. We remind the examiner, as set forth in In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993):

When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement.

For the foregoing reasons, we reverse the rejection of claims 25-39 under the enablement provision of 35 U.S.C. § 112, first paragraph.

<u>SUMMARY</u>

We reverse the rejection of claims 2, 3, 7-17, 25-28, and 37-39 under 35 U.S.C. § 112, second paragraph.

We reverse the rejection of claims 14-17 and 22-39 under the written description provision of 35 U.S.C. § 112, first paragraph.

We reverse the rejection of claims 25-39 under the enablement provision of 35 U.S.C. § 112, first paragraph.

We do not reach the merits of the objection to claim 24, which was not presented for our review.

REVERSED

Toni R. Scheiner

Administrative Patent Judge

) BOARD OF PATENT

APPEALS AND

INTERFERENCES

Donald E. Adams

Administrative Patent Judge

Lora M. Green

Administrative Patent Judge

Appeal No. 2004-1503 Application No. 09/606,808

Robert E. Hanson FULBRIGHT & JAWORSKI L.L.P. A REGISTERED LIMITED LIABILITY PARTNERSHIP 600 CONGRESS AVENUE, SUITE 2400 AUSTIN, TX 78701